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Case No.: 58852US004

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

First Named Inventor: PURKINS, GRAHAM

Application No.: 10/561655 Confirmation No.: 7781

Filed: 14-JUN-2004 Group Art Unit 3754

Title: MULTI-COMPONENT VALVE STEMS

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**BRIEF ON APPEAL**

Mail Stop: Appeal Brief-Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**CERTIFICATE OF MAILING OR TRANSMISSION [37 CFR § 1.8(a)]**

I hereby certify that this correspondence is being:

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July 16, 2010  
Date

/Rebecca C. Bode/  
Signed by: Rebecca C. Bode

Dear Sir:

This is an appeal from the Office Action mailed on December 28, 2009, finally rejecting claims 1–8 and 15–21. This brief is being filed concurrently with a request for a two month extension of time.

**Fees**

- Any required fee under 37 CFR § 41.20(b)(2) will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.17 which may be required to Deposit Account No. 13-3723.
- Please charge any fees under 37 CFR §§ 37 CFR § 41.20(b)(2) and 1.17 which may be required to Deposit Account No. 13-3723.
- Please charge any additional fees associated with the prosecution of this application to Deposit Account No. 13-3723. This authorization includes the fee for any necessary extension of time under 37 CFR § 1.136(a). To the extent any such extension should become necessary, it is hereby requested.
- Please credit any overpayment to the same deposit account.

A Notice of Appeal in this application was filed on March 29, 2010, and was received in the USPTO on March 29, 2010.

**REAL PARTY IN INTEREST**

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

**RELATED APPEALS AND INTERFERENCES**

Appellants are unaware of any related appeals or interferences.

**STATUS OF CLAIMS**

Claims 1–8 and 15–21 are pending. Claims 9–14 are withdrawn. Claims 1–8 and 15–21 stand rejected.

**STATUS OF AMENDMENTS**

No amendments have been filed after the final rejection.

**SUMMARY OF CLAIMED SUBJECT MATTER**

The claims at issue concern an aerosol valve stem (page 1, lines 5 to 7; page 13, lines 18 to 25) for use with a metering valve (page 3, lines 12 to 13; Reference numeral 13, Figures 2A, 2B, and 3A), said valve stem comprising an elongate stem element (page 3, line 13; Reference numeral 12, Figures 2A, 2B, 3A, 3B, and 4; page 6, lines 13 and 14; page 7, line 5 to page 8, line 3) having an elastomeric sleeve (page 6, line 29 to page 7, line 3; page 8, line 5 to page 9, line 20; page 9, line 29 to page 10, line 28) molded onto at least a portion thereof (page 3, lines 13 to 14; Reference numerals 9 and 11, Figures 2A, 2B, 3A, 3B, and 4; page 6, lines 13 and 14; page 6, lines 18 to 20; page 7, line 5 to page 8, line 3) and a sealing element (Reference numerals 16 and 18, Figures 2A, 2B, 3A, 3B, and 4; page 6, lines 14 and 15; page 6, lines 20 to 29; page 10, line 30 to page 11, line 21) having an inner surface (page 3, lines 14 to 15; Reference numeral 7, Figures 2A, 2B, 3A, 3B, and 4), said sealing element being affixed onto the elongate stem element (page 3, line 15; Figures 2A, 2B, 3A, 3B, and 4; page 7, line 5 to page 8, line 3), such that at least a portion of the inner surface of the sealing element is overlying at least a portion of

the elastomeric sleeve (page 3, lines 15 to 17; Figures 2A, 2B, 3A, 3B, and 4; page 6, lines 15 to 17; page 6, lines 20 to 29; page 7, line 5 to page 8, line 3).

### **GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

#### **First Ground of Rejection**

Claims 1, 2, 5–8, and 15–19 stand rejected under 35 USC § 103(a) as purportedly unpatentable over the combined teachings of U.S. Patent 5,772,085 (hereinafter Bryant), and U.S. Patent 4,522,374 (hereinafter Neff).

#### **Second Ground of Rejection**

Claims 3 and 4 stand rejected under 35 USC § 103(a) as purportedly unpatentable over the combined teachings of Bryant, Neff, and U.S. Patent Publication 2002/0020721 (hereinafter Bonningue).

#### **Third Ground of Rejection**

Claims 20 and 21 stand rejected under 35 USC § 103(a) as purportedly unpatentable over the combined teachings of Bryant, Neff, and U.S. Patent 6,739,333 (hereinafter Hoelz).

### **ARGUMENT**

#### **First Ground of Rejection**

Claims 1, 2, 5–8, and 15–19 stand rejected under 35 USC § 103(a) as purportedly unpatentable over the combined teachings of Bryant and Neff. Applicants respectfully submit that the Patent Office has failed to establish a *prima facie* case of obviousness by virtue of its reliance non-analogous art, and its failure to show that a person of ordinary skill in the art would have a reasonable expectation of success for the asserted combination of features.

The MPEP requires at § 2141.01(a) that the Examiner must determine what is “analogous prior art” for the purpose of analyzing the obviousness of the subject matter at issue. MPEP § 2141.01(a). While it is true that a reference in a field different from that of an Applicant’s claimed invention may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his or her invention as a whole, differences in structure *and function* of the invention as claimed and the prior

art are given great weight. See *In re Ellis*, 476 F.2d 1370, 1372, 177 USPQ 526, 527 (CCPA 1973); MPEP 2141.01(a).

In the present appeal, the subject matter of the claims is directed to an aerosol valve stem. Such valve stems are useful, for instance, in metered dose dispensing devices. See claim 15. Such metered dose dispensing devices may include those used for delivering medicaments. See page 9, lines 7 to 8. These aerosol valve stems should meet performance requirements that are unique to the delivery of aerosol medicament doses. Such aerosol valve stems are highly specialized with unique requirements regarding leakage rates, interactions with formulation, force-to-fire, through-life dose consistency, and the like. Indeed, regulatory approval of such devices requires such properties. These functions are very different than the directional, reversing flow control function of the valve spool described in Neff.

Given the very different environment and expected function of aerosol valves as claimed compared to the simple directional, reversing flow control function expected of the spool valves of Neff, Applicants respectfully submit that Neff constitutes non-analogous art to the presently claimed invention.

Even if Neff, by simple virtue of the fact that it refers to a valve stem generally, is considered to be analogous art to the presently claimed invention, Applicants respectfully submit that one of ordinary skill in the art would have no reasonable expectation of success in modifying the teachings of Bryant as provided by Neff, in the manner suggested by the Patent Office. In particular, because nothing in Neff indicates the ability of the spool valve described therein to perform under the demanding requirements of an aerosol valve stem, the Patent Office must make a showing of why one of skill in the art would nonetheless presume that they would. The Patent Office has not even attempted to do so. The Patent Office does provide the conclusory assertion that one of skill in the art would so combine the references “in order to improve the sealing properties of the valve.” While this may serve as a motivation for the combination, the Patent Office does not even address the reasonable expectation of success. Accordingly, the Patent Office has failed to establish a *prima facie* showing of obviousness.

The rejection of claim 1 under 35 USC § 103(a), should be reversed.

Claims 2, 5–8, and 15–19 ultimately depend from independent claim 1 and add patentable features thereto. For at least the reasons articulated above with regard to the failure of

the Patent Office to establish a prima facie showing of obviousness for claim 1, the rejection of claims 2, 5–8, and 15–19 should similarly be reversed.

### **Second Ground of Rejection**

Claims 3 and 4 stand rejected under 35 USC § 103(a) as purportedly unpatentable over the combined teachings of Bryant, Neff, and Bonningue.

Claims 3 and 4 ultimately depend from independent claim 1 and add patentable features thereto. For at least the reasons articulated above with regard to the failure of the Patent Office to establish a prima facie showing of obviousness for claim 1, the rejection of claims 3 and 4 should similarly be reversed.

### **Third Ground of Rejection**

Claims 20 and 21 stand rejected under 35 USC § 103(a) as purportedly unpatentable over the combined teachings of Bryant, Neff, and Hoelz.

Claims 20 and 21 ultimately depend from independent claim 1 and add patentable features thereto. For at least the reasons articulated above with regard to the failure of the Patent Office to establish a prima facie showing of obviousness for claim 1, the rejection of claims 3 and 4 should similarly be reversed.

### **CONCLUSION**

For the foregoing reasons, appellants respectfully submit that the Examiner has erred in rejecting this application. Please reverse the Examiner on all counts.

Respectfully submitted,

July 16, 2010

Date

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**CLAIMS APPENDIX**

1. (Previously Presented) An aerosol valve stem for use with a metering valve, said valve stem comprising an elongate stem element having an elastomeric sleeve molded onto at least a portion thereof and a sealing element having an inner surface, said sealing element being affixed onto the elongate stem element, such that at least a portion of the inner surface of the sealing element is overlying at least a portion of the elastomeric sleeve.
2. (Original) A valve stem according to claim 1, wherein the elongate stem element is made of a metal or a material comprising a polymer.
3. (Original) A valve stem according to claim 2, wherein the elongate stem element is made of a material comprising a polymer and the elastomeric sleeve is co-molded onto at least a portion of the elongate stem element.
4. (Previously Presented) A valve stem according to claim 1, wherein the elongate stem element is made of a material comprising a thermoplastic polymer.
5. (Previously Presented) A valve stem according to claim 1, wherein the elastomeric sleeve is made of a material comprising a thermoplastic elastomer.
6. (Previously Presented) A valve stem according to claim 1, wherein the sealing element is elastomeric.
7. (Previously Presented) A valve stem according to claim 1, wherein the sealing element is made of a material comprising a thermoplastic elastomer or thermoset elastomer.
8. (Original) A valve stem according to claim 6, wherein the sealing element is made of a material comprising a thermoset elastomer selected from EPDM, nitrile, butyl rubber, chlorobutyl rubber, bromobutyl rubber and neoprene.

9. (Withdrawn) A method of manufacturing a valve stem for use with a metering valve, said valve stem comprising an elongate stem element, an elastomeric sleeve and a sealing element, said method comprising the steps of:
  - a) providing an elongate stem element;
  - b) providing a mold shape containing at least in part the elongate stem element;
  - c) molding a material to form the elastomeric sleeve, such that the elastomeric sleeve is molded onto at least a portion of the elongate stem element; and
  - d) affixing the sealing element onto the elongate stem element, such at least a portion of the inner surface of the sealing element is overlying at least a portion of the elastomeric sleeve.
10. (Withdrawn) A method of manufacturing a valve stem according to claim 9, wherein said mold shape and said material is the second mold shape and second material; wherein the elongate stem element made of a first material comprising a polymer and step a) of providing an elongate stem element comprising the steps of:
  - i) providing a first mold shape;
  - ii) molding a first material to form the elongate stem element,and wherein in step c) molding is performed, such that the elastomeric sleeve is co-molded onto at least a portion of the elongate stem element.
11. (Withdrawn) A method of manufacturing a valve stem for use with a metering valve, said valve stem comprising an elongate stem element, said elongate stem element made of a first material comprising a polymer, an elastomeric sleeve and a sealing element, said method comprising the steps of:
  - a) providing a second mold shape;
  - b) molding a second material to form the elastomeric sleeve;
  - c) providing a first mold shape underlying at least in part the elastomeric sleeve; and
  - d) molding a first material comprising a polymer to form the elongate stem element having the elastomeric sleeve co-molded onto at least a portion of said elongate stem element;

e) affixing the sealing element onto the elongate stem element, such at least a portion of the inner surface of the sealing element is overlying at least a portion of the elastomeric sleeve.

12. (Withdrawn) A method of manufacturing according to claim 10, wherein the step of molding elongate stem element is injection molding.

13. (Withdrawn) A method of manufacturing according to claim 9, wherein the second material comprises a thermoplastic elastomer.

14. (Withdrawn) A method of manufacturing according to claim 9, wherein the step of molding the elastomeric sleeve is injection molding.

15. (Previously Presented) A metered dose dispensing valve comprising a valve stem according to claim 1.

16. (Original) A metered dose dispensing valve according to claim 15, said valve being suitable for dispensing metered volumes of a pressurized aerosol formulation and wherein said valve further comprises a chamber and an outlet passage, wherein the valve stem extends into the chamber and is movable relative to the chamber between non-dispensing and dispensing positions, the valve stem having a configuration including an external surface and the chamber having an internal configuration including an internal surface such that a movable metered volume of pressurized aerosol formulation is capable of being defined therebetween and such that during the movement between its non-dispensing and dispensing positions the valve stem sequentially:

- i) allows free flow of aerosol formulation into and out of the chamber;
- ii) defines a closed metered volume for pressurized aerosol formulation between the external surface of the valve stem and internal surface of the chamber, and
- iii) moves with the closed metered volume within the chamber without decreasing the volume of the closed metered volume until the metered volume communicates with the

outlet passage thereby allowing dispensing of the metered volume of pressurized aerosol formulation.

17. (Original) A metered dose dispensing valve according to claim 16, wherein said valve stem a second elastomeric sleeve, said second elastomeric sleeve molded onto at least a portion thereof, and a second sealing element, said second sealing element having an inner surface and being arranged and affixed onto the elongate stem element, such that at least a portion of the inner surface of the sealing element is overlying at least a portion of the elastomeric sleeve, and being longitudinally spaced from the first sealing element, each sealing element having a sealing surface capable of forming a gas-tight seal with the internal surface of the chamber.
18. (Previously Presented) A metered dose dispenser comprising a container equipped with a metered dose dispensing valve according to claim 15.
19. (Original) A metered dose dispenser according to claim 18, wherein the container contains a medicinal aerosol formulation.
20. (Original) A metered dose dispenser according to claim 19, wherein the medicinal aerosol formulation comprises a medicament and a propellant selected from 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof.
21. (Original) A metered dose dispenser according to claim 20, wherein the formulation further comprises ethanol.

**EVIDENCE APPENDIX**

None.

**RELATED PROCEEDINGS APPENDIX**

None.